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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,714	DEBRUYNE ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38,40-48 and 51-53* is/are pending in the application.

4a) Of the above claim(s) *47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,40-46 and 51-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 38, 40-46, and 50-53 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In regards to claims 38 and 52, the Examiner was unable to find support for the combination of elements including the claimed range of "at least a majority of the circumference of the lead" (i.e., 50-100% of the lead).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

> granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 38, 40, 42-45, 51, and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Kramm et al. (US 6,936,040, hereinafter "Kramm").

6. In regards to claim 38, Kramm discloses an implantable system comprising a lead (proximal portion of 14); a resiliently flexible member extending from the lead and having an electrode capable of delivering electrical stimulation signals from any type of source applied, including a speech processor (distal end of 14; col. 5, lines 37-39; the claim language does not require that the signals are in any way efficacious); a bioactive substance delivery means (Fig. 3) adapted to deliver a substance at a location spaced from the distal end of the member during or following implantation (col. 5, lines 37-39; when the lead is "directed out of the distal end" of the catheter); wherein the delivery means comprises a body defining a chamber (56 and 48) and an outlet (surface of 48) and wherein the body is relatively slidably mounted to the lead (col. 5, lines 37-39). Furthermore, the delivery means is configured to completely surround the lead (Fig. 3).

7. In regards to claims 40, Kramm's electrode device is necessarily capable of being positionable outside and adjacent a cochleostomy site because the claim does not actually require a hearing aid device (i.e., an electrode is capable of passing electrical signals regardless of its intended use), and Kramm's device is of a size capable of being placed in a cochlea because it is of a size capable of placement in the similar-dimensioned coronary vasculature. Furthermore, the claim language does not require a lead or delivery means that is actually configured for placement in a cochlea,

but only a substance delivery means capable of placement external and adjacent to a cochleostomy site.

8. In regards to claim 42, the body comprises an annular member positioned completely around the lead (42 and 50).

9. In regards to claim 43, the annular member has a first and second portion having different ODs (42 and 50).

10. In regards to claim 44, the outlet of the body (48) is positioned in the distal end and the body includes an inlet at the proximal end (54).

11. In regards to claim 45, the lumen/chamber acts as a reservoir and the substance leaches from the chamber into the tissue (col. 6, lines 45-50).

12. In regards to claim 51, the delivery means is adapted to deliver the substance at a location spaced from the distal end of the member during and following implantation (when the lead is advanced distally of 48).

13. In regards to claim 52, the chamber surrounds a majority of the circumference of the lead (Figs. 3 and 6).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 53 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kramm. Kramm discloses the essential features of the claimed invention including a chamber (48) that appears to completely surround the lead (Fig. 6). In the alternative, Kramm discloses the essential features of the claimed invention except for explicitly indicating that the chamber completely surrounds the lead. It is well known in the art to provide drug delivery means that surround the entire lead to provide the predictable result of even and complete drug delivery at the site of implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kramm's invention by providing a chamber that surrounds the entire lead to provide the predictable result of even and complete drug delivery at the site of implantation. Furthermore, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the chamber as taught by Kramm by totally surrounding the lead because applicant has not disclosed that this provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform

equally well with the system as taught by Kramm because both systems effectively deliver drug to the site of implantation. Therefore, it would have been an obvious matter of design choice to modify Kramm's invention to obtain the invention as specified in the claims.

17. Claims 38, 40, 44, 45, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma et al. (US 6,309,410, hereinafter "Kuzma"), or in the alternative, under 35 U.S.C. 103(a) as being unpatentable in view of Kuzma and Kuzma (US 6,321,125, hereinafter "Kuzma II").

18. In regards to claim 38, Kuzma discloses an implantable stimulating device comprising a lead (proximal portion of 10); a resiliently flexible elongate member extending from the lead having at least one electrode for delivering stimulation sepcifed by a speech processor (distal portion of 10 and elements 200); a bioactive delivery means (20, see 25' in Fig. 2B) adapted to deliver a bioactive substance at a location spaced from the distal end of the member (Fig. 2A), and wherein the substance delivery means comprises a body having a chamber (lumen 25') and an outlet (col. 6, lines 18-22); and further wherein the body is relatively slidably mounted to the lead of the device (Fig. 2B and col. 4, lines 19-29). Furthermore, Kuzma's substance delivery means is configured to surround at least a majority of the circumference of the lead as shown in, e.g., Figures 2A and 2B. For instance, the delivery means is actually in contact with what appears to be slightly less than a majority of the lead in Fig. 2B, but due to the spiral configuration of the system, as shown in, e.g., Fig. 2A, a portion of the delivery means "surrounds" the lead (but is not in actual contact with the lead due to the

intervening tissue). In other words, the delivery means surrounds the lead both in the region of contact with the lead and the portion that is not in contact, but nonetheless "surrounds" the lead by virtue of the spiral configuration. In the alternative, Kuzma discloses the essential features of the claimed invention except for explicitly indicating that the spacer/delivery means surrounds at least a majority of the lead. Kuzma II teaches a similar cochlear implant system wherein the spacer surrounds at least a majority of the lead (Fig. 7; elements 122a, 122b, 123a, and 123b) to provide the predictable result of maintaining the spacer alongside the lead (col. 10, lines 38-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kuzma's invention by providing a delivery means that surrounds at least a majority of the lead to provide the predictable result of maintaining the delivery means alongside the lead.

19. In regards to claims 40 and51, the outlet of the substance delivery means is positionable outside and adjacent a cochleostomy site, for instance, right as the positioner is inserted behind the electrode carrier. The Examiner is considering "after implantation" to include a state wherein the lead is fully inserted and the delivery means is partially inserted.

20. In regards to claim 44, Kuzma discloses that the drug delivery channel passes "longitudinally through" (col. 6, lines 3-21) the device, and thus the outlet is in the distal end of the body and the body includes an inlet in the proximal end (Figs. 2A and 2B).

21. In regards to claim 45, Kuzma discloses that the channel may be provided with small openings to leach the drug from the channel (col. 6, lines 13-19).

22. Claims 41 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma (or Kuzma in view of Kuzma II). Kuzma (or Kuzma and Kuzma II) discloses the essential features of the claimed invention except for a “stop” on the lead that prevents the substance delivery means from moving past the stop means; or an outlet that includes a semi-permeable membrane. It is well known in the cochlear stimulation arts to provide stops on leads that prevent positioning devices, such as Kuzma's, from moving past the stop means to provide the predictable result of avoiding damage to the cochlea and ensuring proper placement of the electrodes relative to the positioner; and to provide drug outlets that include semi-permeable membranes to provide the predictable result of releasing drugs at a specifically desired rate. Therefore, it would have been obvious to one having ordinary skill at the time the invention was made to provide Kuzma's invention with a stop on the lead that prevents the positioning device from moving past the stop means to provide the predictable result of avoiding damage to the cochlea and ensuring proper placement of the electrodes relative to the positioner; and to provide a drug outlet that includes a semi-permeable membrane to provide the predictable result of releasing drugs at a specifically desired rate.

Response to Arguments

23. Applicant's arguments filed 8/6/2009 have been fully considered but they are not persuasive. Applicant argued that Kuzma fails to disclose a means that surrounds at least a majority of the circumference of the lead. However, please see the new grounds of rejection above. Applicant further argued that Kramm is drawn to heart stimulation and not stimulation "specified at least in part by a speech processor." However the

claim does not positively recite a speech processor and only requires an electrode capable of delivering a signal "specified at least in part by a speech processor." As the claim does not require any sort of efficacy provided by this signal (i.e., the applied signal need not produce auditory effects in a patient), the Examiner is of the position that this signal or any other signal could be applied to Kramm's heart electrode.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Skalsky et al. (US 4,784,161) is one of many teachings of a drug reservoir that completely surrounds a lead (Fig. 23).

25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

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